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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,426	08/21/2003	Michael Seul	LEAPS-C11	8876

7590 09/11/2006

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EXAMINER
DO, PENSEE T

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,426	SEUL, MICHAEL	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *June 9, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2006 has been entered.

Amendment Entry & Claim Status

The amendment filed on May 16, 2006 has been acknowledged and entered.

Claims 76-92 are pending.

Withdrawn Rejection(s)

Rejection under 102 by Gombinski in the previous office action is withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 81-83, "proteins" and "oligonucleotides" lack antecedent basis. If Applicants intend to recite the ligands comprise proteins or oligonucleotides, please clarify.

Claims 81 and 83, please change "An array" to –The array—for proper antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76-84,86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer et al. (5,573,909).

Margel teaches a composition comprising: a) a substrate such as silicon wafer (silicon substrate of claims 84, semiconductor), glass, or wells of Eliza plate in a planar array (col. 11-12, example 31); It is inherent that wells of an Eliza plate are at discrete sites; b) a population of particles randomly distributed on said sites or wells, said population comprises a plurality of different types of particles with chemical or biochemical binding sites/ligands. (see col. 2, line 35-col. 3, line 5; col. 4, lines 25-65). Regarding claim 88, Margel teaches that immobilization is by chemical bonding or physical bonding. (see col. 3, lines 35-36). The ligands are protein/antibody and biological cells. (see col. 1, lines 40-45; col. 3, lines 23-27). Regarding claim 82, since

Margel teaches the use of antibody specific for T-lymphocytes, it is inherent that Margel teaches using monoclonal antibodies because monoclonal antibodies are specific for a cell type. Margel teaches that 1,300 picomoles per squared centimeter protein was bonded to each of the supported microsphere system (see col. 11, lines 7-9).

However, Margel fails to teach each type of particle comprises a distinct chemical or biochemical binding site and comprises a unique chemical label; the biochemical binding site comprises a nucleic acid and particles are exposed to a sample containing target analyte.

Singer teaches microparticles having detectably distinct spectral characteristics of a plurality of dyes incorporated into the microparticles that provide a large and effective Stokes shift, wherein in one example a microparticle-labeled probe emits green fluorescence and another microparticle-labeled probe emits red fluorescence, wherein each microparticle with a distinct spectral characteristic is labeled with a different target complement (biochemical binding sites) to bind with different targets in a sample (claim 89). (see col. 1, lines 32-34, col. 4, lines 37-67, col. 13, lines 53-56; col. 16, lines 54-65). Singer also teaches that the microspheres are polyacrolein or polystyrene and that the target and target complement are antibodies and proteins, respectively. (see col. 13, lines 60-63, col. 16, lines 3 and 31). Singer also teaches that a nucleic acid probe on the microparticles are selective for target nucleic acids. (see col. 14, lines 15-62, col. 16, lines 9-12, and 40-43; col. 18, lines 49-51).

It would have been obvious to one of ordinary skills in the art to modify the composition of Margel with microparticles having distinct spectral characteristics of a

plurality of dyes incorporated into the microparticles and each microparticle is labeled with a different target complement for detecting different target materials in a sample, and such target complement is a nucleic acid as taught by Singer, in order to detect one or more variety of target materials including nucleic acids simultaneously and with high sensitivity since both references teach polyacrolein and polystyrene particles that can immobilize antibodies.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer as applied to claim 76 above, and further in view of Nacamulli et al. (US 5,527,710).

Margel and Singer have been discussed above.

However, Margel and Singer fail to teach that the substrate is an electrode.

Nacamulli teaches antigen coated magnetic particles (particle-attached ligands) are deposited uniformly onto the working electrode from a flow stream by placing the magnet directly below. Electrochemiluminescent labeled antibodies are added and the labeled antibodies to the antigens on the magnetic bead immobilized on the surface of the electrode. (see col. 3, lines 10-30).

It would have been obvious to one of ordinary skills in the art to use the electrode taught by Nacamulli as a substrate for use in the composition taught by Margel and Singer since Margel teaches that the population of particles can be immobilized on semiconductor substrate and Singer teaches that the particles are encoded with labels such as fluorescent labels which are the same as electrochemiluminescent labels and Nacmulli teaches that detection ECL labels requires as substrate such as an electrode

because electrical pulses are needed to apply in order to modulate the ECL output. The ECL signals are useful in monitoring the rates of binding between the proteins/reactants as well as detecting a low concentration of sample.

Claims 91 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer as applied to claim 76 above, and further in view of Gombinski (US 6,297,062).

Margel and Singer have been discussed above.

However, Margel and Singer fail to teach an article of manufacture composition comprising two or more of any of the array defined in claims 76 to 90; and the location of the array on said substrate in combination with the chemical or physical characteristic indicates the types of ligands therein.

Gombinski teaches a matrix comprising of several arrays comprising particles positioned randomly on those array. (see fig. 2, col. 12, lines 15-31). Gombinski also teaches that the location of the array can be stained with a dye or a label so that it can be identified. (see col. 7, lines 16-20).

It would have been obvious to one of ordinary skills in the art to produce several of the arrays taught by Margel and Singer as suggested by Gombinski to accommodate assays of different types of ligands.

Response to Arguments

Applicant's arguments with respect to claims 76-92 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
August 31, 2006

LONG V. LE
SUPERVISORY PATENT EXAMINER
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